

**K253077 uOmnispace.MR**Apr 22, 2026  
211 days to decisionK253077 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k253077/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Sep 23, 2025
Decision date	Apr 22, 2026
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shanghai United Imaging Healthcare Co., Ltd.</b>
Location	Shanghai, CN
Contact	Xin Gao
Website	<a href="https://www.united-imaging.com">https://www.united-imaging.com</a>
510(k) history	82 submissions · 82 cleared · 2018-2026

Shanghai United Imaging Healthcare Co., Ltd. is a medical imaging company based in Shanghai, China. The company develops and manufactures advanced diagnostic imaging systems and related technologies. The company has received FDA 510(k) clearances from total submissions, with all submissions focused on Radiology devices. FDA 510(k) clearances span from 2018 to 2026, demonstrating sustained regulatory activity and recent market approvals. Recent cleared devices include advanced imaging systems such as magnetic resonance imaging (MRI) platforms, computed tomography (CT) scan...